IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA
BRUNSWICK DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	CIVIL ACTION NO. 2:20cv81
	)	
v.	)	
	)	
HELLER FAMILY MEDICINE LLC, and DR. JENNIFER HELLER, D.C.,	)	
	)	
	)	
Defendants.	)	

UNITED STATES OF AMERICA'S COMPLAINT

The United States of America brings this action to recover losses from false claims submitted to the Medicare Program by Defendants Heller Family Medicine, LLC and Jennifer Heller, D.C. ("Dr. Heller") (collectively "Defendants") for "procedures" performed with an acupuncture device and fraudulently billed under Healthcare Common Procedure Coding System L8679 (Implantable neurostimulator, pulse generator, any type). Over a two-year period, Medicare paid Defendants $1,434,798.45 for these fraudulent claims.

I. THE PARTIES

1. Plaintiff, the United States of America, brings this action on behalf of the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS), on behalf of the Medicare Program.

2. Defendant Heller Family Medicine, is a Georgia Limited Liability Company with a principal place of business at 208 Scranton Connector, Suite 120, Brunswick, GA, 31525.

3. Defendant Jennifer Heller, D.C., is a licensed chiropractor and the owner of Heller Family Medicine, LLC. Dr. Heller is a Georgia resident and resides in the Brunswick Division of the Southern District of Georgia.

III. JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345. This civil action arises under the laws of the United States, and this civil action is brought by the United States as a plaintiff pursuant to the FCA.

5. The Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because Defendants can be found in and/or have transacted business within the Southern District of Georgia.

6. Venue is proper in the Southern District of Georgia under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1395(a) because Defendants can be found in and/or have transacted business in the district. Defendants regularly conducted substantial business within the district, maintained employees and offices within the district, and/or generated significant revenue from work performed within the district.

IV. THE LAW.

THE FCA

7. The FCA provides, in pertinent part, that any person who:

> "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent; [or]

(C) conspires to commit a violation of subparagraph (A) [or] (B . . .

is liable to the United States Government [for statutory damages and such penalties as are allowed by law]." 31 U.S.C. §§ 3729(a)(1)-(3) (2006), as amended by 31 U.S.C. § 3729(a)(1)(A)-(C) (2010).

8. The FCA further provides that "knowing" and "knowingly"

"(A) means that a person, with respect to information—

i. has actual knowledge of the information;
ii. acts in deliberate ignorance of the truth or falsity of the information; or
iii. acts in reckless disregard of the truth or falsity of the information; and

(B) requires no specific intent to defraud."

31 U.S.C. § 3729(b) (2006), as amended by 31 U.S.C. § 3729(b)(1) (2010).

9. The FCA, 31 U.S.C. § 3729(a)(1), provides that any person who violates the Act is liable to the United States Government for three times the amount of damages which the Government sustains because of the act of that person, plus a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990. *See* 28 C.F.R. § 85.5 (setting forth the current penalties level of not less than $11,665 and not more than $23,331 for violations of the FCA).

10. In 1965, Congress enacted Title XVIII of the Social Security Act (the "Act"), 42 U.S.C. § 1395 *et seq.*, to provide health insurance coverage for people 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 426, 426a.

11. Medicare is administrated by CMS, which is part of HHS. At all times

relevant to this complaint, CMS contracted with private contractors referred to as "fiscal intermediaries," "carriers," and Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100.

12. Medicare provides coverage for items and services that are reasonable and necessary to diagnose or treat an illness or injury or to improve a malformed body member. Payment will be provided if medical necessity can be substantiated. Section 1862(a)(1) of the Social Security Act. CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Ch. 16, sec. 20.

13. The Medicare Program consists of four parts: A, B, C, and D. As alleged herein, Defendants submitted, or caused to be submitted, false claims under Medicare Part B.

14. Medicare Part B covers medically necessary services, including provider visits, diagnostic tools that meet accepted standards for medical practice, procedures, medical supplies and DME.

15. For a health care provider to seek reimbursement from the Medicare Program, the provider must obtain a National Provider Identifier ("NPI") from CMS. The provider also must submit an enrollment application.

16. Once the provider is enrolled, the provider may submit bills to the Medicare Program for services rendered to the patients. A participating provider must properly document in the patient's medical record the service or procedure performed. 42 C.F.R. § 431.107(b)(1).

17. Medicare only pays for Part B services that are actually rendered and are

reasonable and medically necessary. 42 U.S.C. § 1395y(a). Part B providers must certify that services are medically necessary. 42 C.F.R. § 424.24(g)(1).

18. To obtain reimbursement from the Medicare Program, providers submit a claim form, which is typically done electronically. In particular, providers submit CMS Form 1500 and/or its equivalent, known as the 837P form, which contains the following certifications:

> "In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate, and complete; 2) I have familiarized myself with all applicable laws, regulations and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were incident to my professional service by my employee under my direct supervisor, except as otherwise permitted by Medicare or TRICARE . . . .
>
> NOTICE: Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by the form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

19. Among the information the provider includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology ("CPT") and Healthcare Common Procedure Coding System ("HCPCS") codes, that identify the diagnosis, services rendered and for which reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source." 45 C.F.R. § 162.1002(a)-(b); Medicare Claims Processing Manual, Ch. 23, § 20.7 *et seq*.

20. Providing accurate CPT and HCPCS codes on claims submission forms is

material to and a condition of payment for the Medicare Program. *See, e.g.*, Medicare Learning Network Fact Sheet, Medicare Billing: 837P and Form CMS-1500.

21. The Medicare Program routinely denies payment to providers who bill for codes when the criteria for those codes is not actually met, including when the services are not performed or are not medically necessary.

V. FACTUAL BACKGROUND

22. Dr. Heller is a licensed chiropractor.

23. In early 2016, Dr. Heller began working with an external consultant, "Company-1." Company-1 assists chiropractors developing additional sources of revenue. The relationship was memorialized between Dr. Heller and Company-1 through an April 18, 2016 Independent Contractor Agreement, which Dr. Heller signed through another corporate entity.

24. On April 25, 2016, Dr. Heller created Heller Family Medicine, LLC.

25. Company-1 recommended that Defendants utilize Nurse Practitioners (NPs) and a Medical Director so that Heller Family Medicine could bill private and public healthcare providers for services that a chiropractor, alone, could not.

26. Defendants agreed to this model and Company-1 hired several NPs and a Medical Director. While the NPs and Medical Director were "hired" by Company-1 , they worked in Brunswick for Defendants. The NPs and Medical Director allowed Defendant Heller Family Medicine to perform and bill for services that Dr. Heller could not directly perform or bill for as a chiropractor. These NPs and Medical Director's Medicare payments were assigned to Heller Family Medicine.

27. Defendants paid Company-1 an hourly fee for the NPs and Medical

Director. Company-1, in turn, kept a percentage of this money and paid the NPs and Medical Director the remainder. All revenue derived from the NPs and Medical Director's medical services—whether from the Medicare Program or private payors—was paid directly to Heller Family Medicine.

28. As a way to earn additional revenue, Company-1 suggested that Defendants start using a P-Stim[1] acupuncture device and seek reimbursement from private providers and the Medicare Program for this "service."

29. A P-Stim is an electric acupuncture device that is attached to the ears of the patient using two small pads. This non-covered acupuncture "service" is provided in an office setting.

30. A National Coverage Determination ("NCD") for Acupuncture (30.3) states "acupuncture is not considered reasonable and necessary" within the meaning of Section of 1862(a)(1) of the Social Security Act (the "Act"). This is a long-standing determination and was widely known throughout the relevant time period.

31. Some, if not all, of the devices Defendants used to perform this acupuncture service were made by a company called Stivax.

32. The Stivax website includes a disclaimer stating "[i]t is our understanding that Medicare and some commercial insurance companies are not covering electro-acupuncture or auricular vagus nerve stimulation devices such as Stivax at this time."

33. To circumvent this prohibition against coverage for acupuncture, Defendants billed Medicare using HCPCS L8679 in connection with the P-Stim

[1] Other brand names for the device include Stivax, NeuroStimulator, ANSiStim, E-Pulse and NSS-2 Bridge. All such devices are collectively referred to as "P-Stim."

"treatment." While the P-Stim devices typically cost between $300 and $500, Medicare typically reimburses between $5,000 and $6,500 for HCPCS L8679.

34. HCPCS L8679 is an implantable neurostimulator and pulse generator. This procedure requires the provider perform surgery by making an incision on the patient's back and placing the leads (medical wires) that deliver the stimulation into the epidural space on the spinal cord. Payment for the surgical procedure requires the service to be performed in a surgery center. When billed in an outpatient center HCPCS L8679 is non-payable.

35. Starting in the fall 2016, Defendants began using the P-Stim acupuncture device. Defendants' P-Stim "treatment" was not performed at a surgery center, required no surgical implantation, and merely placed two wires behind the patient's ears. The P-Stim "treatment," therefore, was clearly not covered by HCPCS L8679. Despite this, Defendants repeatedly billed the P-Stim "treatment" to the Medicare Program for HCPCS L8679 by using CMS 1500 Forms containing false information and certifications.

36. Defendants also obtained an NPI for Heller Fancy Medspa, an unincorporated DBA of Heller Family Medicine and submitted HCPCS L8679 claims from it.

37. Based on Defendants' false submissions to Medicare for HCPCS L8679 for the P-Stim treatment, the Medicare Program paid Defendants between $5,800 and $6,400 for each "treatment."

38. After realizing how lucrative the fraudulent P-Stim payments were, Dr. Heller emailed her P-Stim salesperson on March 14, 2017 and told him that she planned

on opening up a medical spa and that she estimated that she would need 20 P-Stim devices per month. Extrapolating Defendants' previous Medicare payments for HCPCS L8679, 20 P-Stim "treatments" per month would result in Medicare payments of $116,000 to $128,000 per month.

39. On March 27, 2017, Defendants, in consultation with Company-1, rolled out a bonus program to incentivize the improper billing of HCPCS L8679. Under the bonus program, Defendants paid NP's, through Company-1, $100 per P-Stim "treatment."

40. On March 14, 2018, Company-1 sent Dr. Heller a "product line update for the Neurostimulator." In this update, Company-1 noted that it "does not have the necessary documentation, or the information that we feel necessary for us to support the use of the neurostimulator products as it relates to coding, billing, and compliance." The update further recommended that Defendants "review the coding, billing, compliance and utilization with your compliance officer, attorney, or other professional that is qualified to give you an opinion as to the appropriate coding, billing, compliance, and utilization of the product."

41. Dr. Heller signed and returned the March 14, 2018 update. Upon information and belief, Defendants, however, never sought the advice of a compliance officer, attorney or other qualified professional to determine whether the P-Stim acupuncture treatment was properly reimbursable by the Medicare Program through HCPCS L8679.

42. Defendants did, however, take out an advertisement in The Brunswick News on June 8, 2018 touting the P-Stim "treatment." In the advertisement, Defendants

described the procedure as "a small, battery powered electronic device that one wears on the ear with a cord attached to the shirt collar." One of Defendants' NPs is quoted in the advertisement as saying "[o]ur Medicare patients have really benefited from this." Defendants took out an additional, similar advertisement in The Brunswick News on September 25, 2018.

43. On July 16, 2018, Dr. Heller emailed and told Company-1 that a friend of hers had been audited and that all money was requested back from the "STIVAX treatment due to invalid coding."

44. Despite the fact that NCD (30.3) states "acupuncture is not considered reasonable and necessary," the warning of Medicare non-coverage from the Stivax website, the clear inapplicability of the surgical code HCPCS L8679 to the P-Stim "treatment," a warning from Company-1, and the fact that Dr. Heller knew a friend was under audit for the "STIVAX treatment," Defendants continued to improperly bill the P-Stim acupuncture "treatment" until October 19, 2018.

45. In total, Defendants were paid $1,434,798.45 for more than three hundred fraudulent P-Stim claims[2] that were falsely certified as "medically necessary" and improperly submitted under HCPCS L8679 through CMS 1500 Forms. *See* Exhibit A. Indeed, two beneficiaries received this treatment 15 times in a single year by Defendants. As a result, Medicare reimbursed Defendants more than $90,000 for each of these beneficiaries.

46. For her part, Dr. Heller made hundreds of thousands of dollars from these improper payments after paying Company-1 and the NPs.

[2] Defendants submitted 304 total P-Stim claims. See Exhibit A. Some of these claims, however, were denied.

47. The United States would not have paid any portion of the $1,434,798.45 to the Defendants had it known Defendants were performing an P-Stim acupuncture "treatment" in an office setting rather than the surgical procedure set forth in HCPCS L8679.

48. CMS demanded that Defendants repay this improperly obtained money. They did not.

Count I
(FCA: Presentment of False Claims (31 U.S.C. § 3729(a)(1)(A))

49. The United States incorporates by reference Paragraphs 1 through 48 above as if fully set forth in this Paragraph.

50. As detailed above, Defendants knowingly presented, or caused to be presented, materially false and fraudulent claims for payment or approval to the United States, including claims for reimbursement by the Medicare Program that were false and fraudulent because they (i) were for services for which the Medicare Program does not reimburse; and/or (ii) were not medically necessary.

51. As detailed above, the Medicare Program would not otherwise have paid for these false and fraudulent claims.

52. Defendants presented or caused to be presented these claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

53. Defendants are liable to the United States for damages in an amount to be determined at trial, but not less than $1,434,798.45 in single damages, trebled, as well as a minimum civil penalty of $11,665 to a maximum penalty of $23,331 for each claim

submitted to the Medicare Program.

Count II
(FCA: Making or Using False Statements Material to a False Claim (31 U.S.C. § 3729(a)(1)(B))

54. The United States incorporates by reference Paragraphs 1 through 48 above as if fully set forth in this Paragraph.

55. As detailed above, Defendants knowingly made, used, or caused to be made or used, false records or statements, which included false certifications and representations on forms CMS 1500 to obtain approval for and payment by the United States for false or fraudulent claims as detailed above.

56. Defendants' false certifications and representations were made for the purpose of ensuring that the Medicare Program paid the false or fraudulent claims, which was a reasonable and foreseeable consequence of Defendants' statements and actions.

57. The false certifications and representations made or caused to be made by Defendants were material to the payment of the false claims by the United States.

58. Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

59. Defendants are liable to the United States for damages in an amount to be determined at trial, but not less than $1,434,798.45 in single damages, trebled, as well as a minimum civil penalty of $11,665 to a maximum penalty of $23,331 for each claim submitted to the Medicare Program.

Count III
(Payment by Mistake)

60. The United States incorporates by reference Paragraphs 1 through 48 above as if fully set forth in this Paragraph.

61. The United States paid Defendants, either directly or indirectly, for claims submitted by Defendant Heller Family Medicine for services that were (i) not medically necessary; and/or (ii) did not otherwise satisfy the requirements of the Medicare Program, without knowledge of material facts, and under the mistaken belief that Defendants were entitled to receive payment for such claims.

62. The mistaken belief of the United States was material to their decision to pay Defendants for such claims.

63. The United States reasonably relied on Defendants' submission of claims that they believed were accurate, complete, and truthful, in accordance with the express requirements of the Medicare Program.

64. The United States has been damaged as a result of this mistaken payment, and the Defendants are thus liable to account and pay to the United States such amounts, which are to be determined at trial.

Count IV
(Unjust Enrichment)

65. The United States incorporates by reference Paragraphs 1 through 48 above as if fully set forth in this Paragraph.

66. By retaining monies and profits received from services that were not reimbursable, Defendants retained money that was the property of the Medicare Program, to which they are not entitled.

67. The United States seek the recovery of all funds paid by the Medicare Program by which Defendants have been unjustly enriched, including profits unlawfully earned for acupuncture that were medically unnecessary and not accurately identified.

68. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the United States in an amount to be determined and which, under the circumstances, in equity and good conscience, should be returned to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Defendants, jointly and severally, as follows:

I. On the First and Second Counts under the FCA for the amount of the United States' damages, trebled as required by law, and such civil penalties as are permitted by law, together with all such relief as may be just and proper.

II. On the Third Count for payment by mistake, for the amounts the United States paid by mistake, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

III. On the Fourth Count for unjust enrichment, for the amounts by which Defendants were unjustly enriched, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR A JURY TRIAL

The United States demands a jury trial.

This 7th day of August, 2020.

Respectfully submitted,

BOBBY L. CHRISTINE
UNITED STATES ATTORNEY

/s/ Patrick J. Schwedler
PATRICK J. SCHWEDLER
Assistant United States Attorney
Georgia Bar No. 812313

/s/ Jonathan A. Porter
JONATHAN A. PORTER
Assistant United States Attorney
Georgia Bar No. 725457

Post Office Box 8970
Savannah, Georgia 31412
Telephone: (912) 652-4422
Facsimile: (912) 652-4227
Patrick.Schwedler@usdoj.gov
Jonathan.Porter@usdoj.gov